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**FAX**

NUMBER OF PAGES INCLUDING COVER: 5

DATE APRIL 13, 2006

TO PATENT EXAMINER: JEANINE ANNE GOLDBERG

FAX NO. 571.273.8300

FROM BEN WANG,
PATENT ATTORNEY
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Re: US Serial No.: 10/796,280 filed: 03/10/2004
Entitled: "GENETIC POLYMORPHISMS ASSOCIATED WITH STENOSIS, METHODS OF DETECTION AND USES THEREOF"
Atty. Docket No.: CL001510ORD

Attached: **RESPONSE TO RESTRICTION REQUIREMENT; TRANSMITTAL FORM**

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# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

Total Number of Pages in This Submission: 5

| | |
|---|---|
| Application Number | 10/798,280 |
| Filing Date | March 10, 2004 |
| First Named Inventor | Michele CARGILL |
| Art Unit | 1634 |
| Examiner Name | Jeanine Anne Goldberg |
| Attorney Docket Number | CL1510ORD |

## ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please identify below):
  Response to restriction requirement (3 pgs); Fax cover sheet (1pg)

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|---|---|---|---|
| Firm Name | Celera Diagnostics | | |
| Signature |  | | |
| Printed name | Ben Wang | | |
| Date | April 13, 2006 | Reg. No. | 41,420 |

## CERTIFICATE OF TRANSMISSION/MAILING

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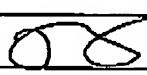
| Signature |  | | |
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Ben Wang

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Cargill, et al.

Art Unit: 1634

Serial No.: 10/796,280

Examiner: Jeanine A. Goldberg

Filed: March 10, 2004

Atty. Docket No.: CL1510ORD

For: GENETIC POLYMORPHISMS ASSOCIATED WITH STENOSIS, METHODS OF DETECTION AND USES THEREOF

Response to Restriction Requirement

**Response to Restriction Requirement under 35 U.S.C. 121**

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

This correspondence is in response to the Restriction Requirement mailed March 13, 2006 for the above-identified application, setting a 30 days/1 month period for the response. The response herein is thus submitted timely.

In the Restriction Requirement, the Examiner requested Applicants elect one of the following inventions:

Group I, Claims 1-6, and 21-22, drawn to a method for identifying an individual who has an altered risk for developing stenosis.

Group II, Claims 7-9, and 13-20, drawn to a nucleic acid.

Group III, Claim 10, drawn to a polypeptide.

Group IV, Claims 11-12, drawn to an antibody.

Group V, Claim 23, drawn to a method for detecting a variant polypeptide.

Group VI, Claim 24, drawn to a method for identifying an agent.

The Examiner also issued a further restriction requirement to all groups having more than one nucleotide sequence.

Applicants hereby provisionally elect, **with traverse**, to prosecute Group I, claims 1-6, and 21-22, drawn to a method for identifying an individual at risk for stenosis, using in particular nucleotide sequence hCV25930271, SEQ ID NO. 19350.

In requiring Applicants to select only one sequence to prosecute, the Examiner noted that "searching more than one of the claimed patentably distinct sequences represents a serious burden for the office." See Restriction Requirement, page 7. Applicants respectfully disagree.

Applicants are mindful of the workload imposed on the Patent Office due to the increasing numbers of patent applications that are being filed and examined. However, Applicants wish to draw the Examiner's attention to MPEP Section 803.04, which addresses restriction requirement relating to nucleotide sequences. See also *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).

There, while recognizing that nucleotide sequences "are deemed to normally constitute independent and distinct inventions", the Director "has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application" in the interest "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office."

The MPEP goes on to announce that it "has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." MPEP Section 803.04, Eighth Edition, Revision 3, August 2005.

Therefore, Applicants hereby respectfully request that the following **ten (10)** nucleotide sequences in Group I to be examined together. The ten sequences are shown in the table attached below. More detailed information about these ten sequences can be found in Table 2, Table 6, Table 7, and the Sequence Listing of the patent specification.

| | Marker | Gene Name | SEQ ID NO. | Source Table |
|---|---|---|---|---|
| 1 | hCV25930271 | LPA | 19350 | 7 |
| 2 | hCV25594325 | HAP1 | 24270 | 6 |
| 3 | hCV25644769 | AP3B1 | 17015 | 6 |
| 4 | hCV25924894 | SERPINA9 | 14931 | 7 |
| 5 | hCV11474611 | CALM1 | 34962 | 7 |
| 6 | hCV11450563 | none | 33563 | 7 |
| 7 | hCV25967803 | EBNA1BP2 | 29980 | 7 |
| 8 | hCV9088175 | TDRKH | 15992 | 7 |
| 9 | hCV16183633 | none | 33679 | 7 |
| 10 | hCV8905006 | PGM1 | 38777 | 7 |

In the event the Examiner maintains the Restriction Requirement, Applicants reserve the right to request rejoinder of any process claims limited in scope to allowable product claims in accordance with *In re Ochiai*, and further reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications without prejudice.

The Examiner is invited to contact the undersigned via telephone if a phone interview would expedite the prosecution of the instant patent application.

Respectfully submitted,

By: _____
Ben Wang, Reg. No.: 41,420

Date: April 13, 2006

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